### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Application No. 10/694,960	) Confirmation No. 1442
Filed:	October 28, 2003	) Confirmation No. 4443 )
Applicants:	Isabelle Laye et al.	)
Title:	PROCESS CHEESE CONTAINING INCREASED LEVELS OF WHEY PROTEIN	) ) )
Art Unit:	1794	)
Examiner:	Leslie A. Wong	) ) )
Attorney Do	cket: 1410/79708	) )
Customer No	o.: 22242	)

Mail Stop AMENDMENT Commissioner for Patents P. O. Box 1450 Alexandria, Virginia 22313-1450

# SUPPLEMENTAL DECLARATION OF DR. ISABELLE LAYE UNDER 37 C.F.R. § 1.132

#### I, DR. ISABELLE LAYE, declare as follows:

- 1. I am one of the inventors of the subject matter claimed in the above-captioned patent application, U.S. Patent Application Serial No. 10/694,960. I have personal knowledge of the matters stated herein and the declarant of the previous declaration dated May 3, 2008 ("Previous Declaration") submitted in this matter.
- 2. The assignee of the above-captioned application is Kraft Foods Holding Inc., which is now Kraft Foods Global Brands LLC ("Kraft Foods"). I am currently employed by Kraft Foods as a Principal Scientist and have worked in the food science field for about 15 years. I have a Ph.D in Food Science and Nutrition from Ohio State University.

- 3. In paragraph 10 of the Previous Declaration, I included a graph comparing the expected melting point ranges for the cheeses described by US Patent No. 5,750,177("Yee") to the melting points obtained from the Inventive cheeses as described in the Example Section of the present application. Attached as Exhibit A hereto is a copy of the Previous Declaration for reference.
- 4. It is my understanding that the Previous Declaration was questioned because it did not explain where the inventive melting points used in the graph of paragraph 10 were obtained from in the specification. This supplemental Declaration addresses these issues by pointing out specifically where the inventive data was described in the specification and better clarifies this data on a supplemental graph.
- 5. In the present specification, we define melting point to be the same as softening point (Specification, p. 14, line 4) and define both as the temperature determined using a Mettler Dropper Point Furnace. (Specification, p. 13, line 29-30.) Yee also measures the melting point using a Mettler dropping point system. (Yee, Col. 8, line 41 to Col. 9, line 20.) As understood by one of ordinary skill, the Mettler equipment measures the temperature at which the cheese falls through an orifice. Therefore, the melting point data of Yee and the melting point data from the Examples in the present specification are both determined using similar test equipment and test methodologies and can be directly compared.
- 6. In this supplemental Declaration, I supplement the graph from my previous declaration with the data of Table 1 below and an expanded, supplemental graph also included below. The data and supplemental graph describe in more detail where I obtained the ratio of casein-to-whey and melting points from the inventive samples used in the prior graph of the Previous Declaration.
- 7. As shown in the graph of FIG. 1 below, this graph is similar to the graph of my Previous Declaration in paragraph 10 of Exhibit A, but I have expanded the X-axis to more clearly show each of the data points from the inventive samples and have labeled each data

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point with the specific Example Numbers from the specification from which it was obtained. For additional summary purposes, the melting points and casein-to-whey ratios for the inventive samples are also provided in Table 1 below, which specifically details the location in the original specification providing support for the data in the graph of FIG. 1 herein. For clarity, the new expanded data in the graph is also provided in red.

**Table 1:** Summary of Casein-to-Whey Ratios and Melting points of Inventive Cheeses as provided in the Examples of the Present Specification

Specification	Casein-to-Whey	Specification	Mettler Melting	Specification
Example	Ratio		Point	
2	56:44 (1.3:1)	p. 15, line 24	135°F	p. 15, line 23
3	62:38 (1.6:1)	p. 16, line 19	147°F	p.16, line 18
4	60:40 (1.5:1)	p. 17, line 21	130°F	p.17, line 20
5	73:27 (2.7:1)	p.18, line 14	130°F	p. 18, line 14
6	70:30 (2.3:1)	p. 19, line 7	110°F	p. 19, line 6

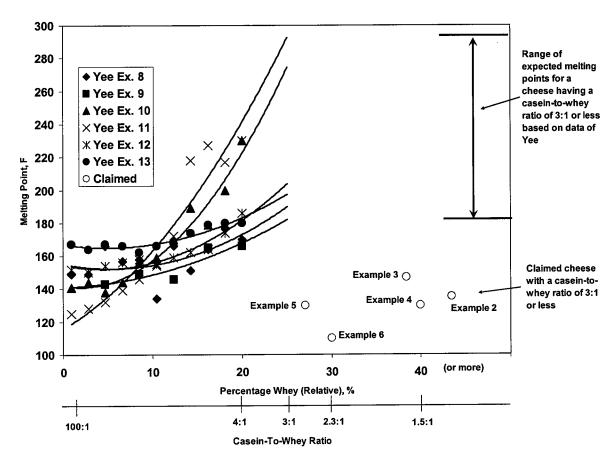


FIG. 1: Supplemental Graph of Yee Melting Points Compared to Inventive Melting Points

- 8. As indicated in my previous declaration of Exhibit A, even though Yee does not describe a cheese or a procedure to produce a processed cheese having a casein-to-whey ratio less than 4:1, if the data of Yee was used to predict the expected melting points for cheese having a casein-to-whey ratio of 3:1 or lower as presently claimed, then the data of Yee suggests such cheese would be expected to have melting points between about 180°F and 290°F as shown in the supplemental Graph above.
- 9. As also shown in the supplemental Graph above, the Examples in the specification of the present application, on the other hand, exhibit Mettler melting points

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between about 105°F to about 150°F. As a result, the claimed cheese exhibits Mettler melting points that are much lower than what is expected based on the data of Examples 8-13 of Yee as plainly shown in the supplemental Graph above.

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity or enforceability of the application or any patent issued thereon.

26 November 2008

Date

Dr. Isabelle Laye

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## **EXHIBIT A**

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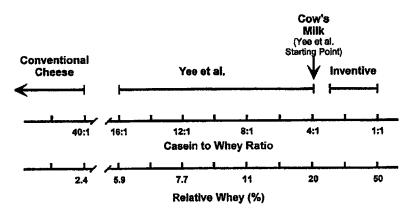
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## DECLARATION OF DR. ISABELLE LAYE UNDER 37 C.F.R. § 1.132

## I, Dr. ISABELLE LAYE, declare as follows:

- 1. I am one of the inventors of the subject matter claimed in the above-captioned patent application, U.S. Patent Application Serial No. 10/694,960. I have personal knowledge of the matters stated herein.
- 2. The assignee of the above-captioned application is Kraft Foods Holding Inc. I am currently employed by Kraft Foods as a Principal Scientist and have worked in the food science field for about 15 years. I have a Ph.D in Food Science and Nutrition from Ohio State University.
  - 3. I have read and understand US 5,750,177 ("Yee").

- 4. Yee states that conventional cheese has a casein-to-whey ratio between about 40:1 and about 150:1 (Yee, Col. 6, lines 8-9) and that typical Cheddar cheese has a casein-to-whey ratio of 100:1 (*Id.*, lines 10-12.). Yee further states that ultrafiltered cheese (UF cheese) has the same ratio of casein-to-whey as its starting raw milk source, which Yee indicates is about 4:1 (*Id.*, Col. 1, lines 25-36 and Col. 26, lines 7-11).
- 5. Yee describes cheese obtained by blending conventional Cheddar cheese with UF cheese in Examples 8 through 13 (*Id.*, Col. 19, line 35 to Col. 25, line 11). Such blended cheese would inherently have a casein-to-whey ratio between 4:1 and 100:1 depending on the amounts of UF cheese and Cheddar cheese in the blend. For example, 100 percent UF cheese would be expected to have a casein-to-whey ratio of 4:1, and 100 percent conventional Cheddar cheese would be expected to have a casein-to-whey ratio of 100:1—blends would be expected to range between these limits. Yee states preferred cheese blends have a casein-to whey ratio of at least about 16:1. (*Id.*, Col. 4, lines 47-50.) Therefore, Yee describes exemplary cheese blends having a casein-to-whey ratio between 100:1 and 4:1 and, preferably, 16:1 to 4:1.
- 6. The cheese claimed in the present patent application has a casein-to-whey ratio from about 50:50 to about 75:25 (*i.e.*, about 1:1 to about 3:1). The Chart below compares the casein-to-whey ratio of the cheese described in Yee to the cheese of the present application. The Chart shows the cheese claimed has a lower casein-to-whey ratio than the cheese described by Yee, which means the claimed cheese has increased amounts of whey.

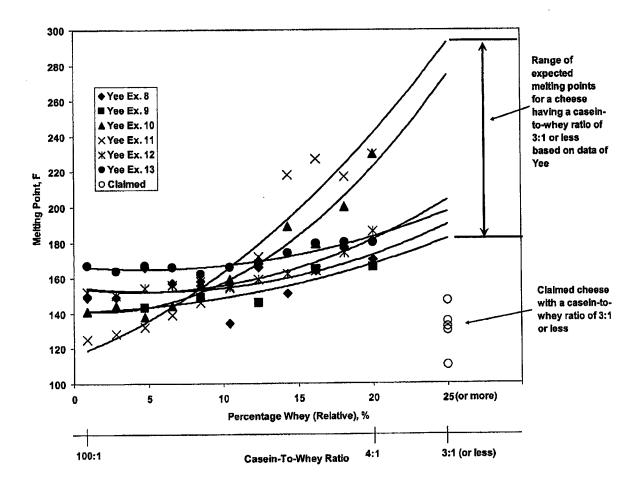


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- 7. The only method described by Yee to increase the level of whey in cheese (and, therefore, lower casein-to-whey ratios) is through ultrafiltration and by blending UF cheese with conventionally prepared cheese. (*See*, e.g, Yee, Col. 10, lines 24-63 and Col. 19, line 35 to Col. 25, line 11.) As stated in Yee and mentioned above, producing a cheese using ultrafiltration results in a casein-to-whey ratio the same as the starting milk source, which is 4:1 or about 20 percent whey (relative<sup>1</sup>). (*Id.*, Col. 26, lines 8-11.) Therefore, Yee does not describe a procedure to obtain a cheese with a casein-to-whey ratio lower than 4:1.
- 8. Yee also provides melting point data of the cheese described in his patent. In Examples 8-13, Yee lists the melting points in Tables 11-16 for blends of conventional cheese and UF cheese ranging from a 100 percent conventional Cheddar cheese/0 percent UF cheese blend to a 0 percent Cheddar cheese/100 percent UF cheese blend. (Yee, Col. 19, line 35 to Col. 25, line 11.) As discussed above, these cheese blends would inherently have a casein-to-whey ratio between 100:1 to 4:1 (depending on the blend).
- 9. The Chart below plots the melting point data from Tables 11-16 of Yee (Cols. 20-23) against the casein-to-whey ratio and the percentage whey (relative) using the Chart function in MS Excel. A polynomial trend line for each Example is also provided using the Trendline function in MS Excel. Each trend line is extrapolated out to a casein-to-whey ratio of 3:1 (or 25 percent relative whey) using the Forecast Forward function in MS Excel.
- 10. For comparison, the melting point data from Examples 1 to 6 of the Exemplary cheese described in the present application is also added to the Chart below. (Specification, pg. 14-19.)<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Relative percentage whey is the amount of whey based on the combined amount of whey and casein. For example, a 4:1 ratio of casein-to-whey has 20 percent relative whey (1 part whey/[5 parts whey and casein] x 100).

<sup>&</sup>lt;sup>2</sup> Example 7 of the present application did not provide melting point data and Example 8 provided such data after a week of storage and was not added to the chart because melting point was measured differently (*i.e.*, after storage). Nevertheless, the melting point of Example 8 was 121°F, which was also within the same range as those provided on the chart.



- 11. Even though Yee does not describe a cheese or a procedure to produce a cheese having a casein-to-whey ratio less than 4:1, if the data of Yee was used to predict the expected melting points for cheese having a casein-to-whey ratio of 3:1 or lower as claimed, then the data of Yee suggests such cheese would have melting points between about 180°F and 290°F as shown in the Chart above.
- 12. As also shown in the Chart above, the claimed cheese, on the other hand, exhibits melting points from about 105 to about 150°F. As a result, the claimed cheese exhibits

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melting points that are much lower than what is expected based on the data of Examples 8-13 of Yee as plainly shown in the Chart above.

13. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity or enforceability of the application or any patent issued thereon.

5/13/20-8

Date

Dr. Isabelle Laye